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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,155	10/01/2001	Ole Sibbesen	078883-0132	9265

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EXAMINER

RAO, MANJUNATH N

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,155

Applicant(s)

SIBBESEN ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 26-34, 36, 38, 39, 41, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11, 27-34, 36, 38, 39, 41, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-8, 11, 26-34, 36, 38-39, 41, 44-45 are presently pending in this application.

Claim 26 is now under consideration. Claims 1-8, 11, 27-34, 36, 38-39 and 41, 44-45 remain withdrawn from consideration as being drawn to non-elected invention.

Applicants' amendments and arguments filed on 5-20-04, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically Examiner has withdrawn the rejections under 35 U.S.C. 112, 1st and 2nd paragraphs in view of claim amendment and arguments presented by the applicant. Examiner has also modified and maintained the rejection of claim 26 under 35 U.S.C. 103(a).

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Based on applicant's showing of support for claim 26 in the priority document UK 9828599, 12-23-1998, Examiner has withdrawn the objection to grant the priority date of 12-23-1998.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rouau et al. (J. Cer. Sci., 1998, Vol. 28 :63-70) or Debyser et al. (WO 98/49278, 11-5-1998). This rejection is based upon the public availability of printed publications. Claim 26 of the instant application is drawn to an a method of using a endo- β -1,4-xylanase inhibitor for determining the degree of resistance of xylanases to an inhibitor wherein said inhibitor is isolated from wheat flour, wherein the inhibitor has a molecular weight of about 40 kDa as measured by MS or SDS PAGE, wherein the inhibitor has a pI of about 8 to about 9.5, and wherein the inhibitor comprises one or more amino acid sequences presented as SEQ ID NO:13 through 19 by contacting the enzyme with the inhibitor and determining the activity of the xylanase and identifying those that are resistant to the action of the inhibitor.

Debyser et al. and Rouau et al. also teach a xylanase inhibitor isolated from wheat flour and determine the degree of resistance of the xylanases towards the inhibition. The references teach that the inhibitor has a molecular weight between 40-43 kDa as determined by SDS PAGE. The references do not explicitly disclose the pI values of the inhibitor protein.

The references clearly teach the importance of xylanase enzymes in the baking industry as well as the importance of its activity in the wheat flour dough. The reference compares several different xylanases in their ability to withstand the action of the inhibitor. However, the references do not explicitly suggest that said inhibitor can be used to identify xylanases that are resistant to its action. Also, the references do not explicitly teach that the inhibitor protein comprises the amino acid sequences with SEQ ID NO:13 through 19. Examiner takes the position that such characteristics of a protein are inherent characteristics and therefore the xylanase inhibitor taught by Debyser et al. and Rouau et al. and that claimed in the above

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method are one and the same (Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594). Furthermore, based on the teachings of Debyser et al. that xylanases are industrially important due to their use in bread-making recipes since they have a positive effect on bread volume and that inhibition of such enzyme would be deleterious to the bread-making efforts, Examiner maintains that it would have been obvious to those skilled in the art to devise methods to identify and select enzymes (xylanases) that are resistant to the inhibitor. Such method would have been obvious because the reference also suggests that the inhibitor is inherently present in wheat flour used in the baking bread. One of ordinary skill in the art would be motivated to do so as the above reference teaches that inhibition of the xylanase enzyme would negatively effect the bread volume and that the inhibitor is inherently presently in the wheat flour. One of ordinary skill in the art would have a reasonable expectation of success since the above reference uses said inhibitor to analyze several types of xylanases for their ability to be inhibited by the inhibitor.

Therefore the above inventions would have been *prima facie* obvious to those skilled in the art.

In response to the previous Office action, applicant has traversed the above rejection arguing that Debyser (a) et al. is not a prior art. Examiner has removed that reference from the rejection and therefore argument traversing the above reference is moot.

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With reference to Debyser et al. (WO 98/49278, 11-5-1998) applicant argues, while the reference does teach an inhibitor of xylanase and its use in food and feed industry, the reference does not teach that the inhibitor is useful to identify and prepare one or more xylanases having high degree of resistance to the inhibitor and that the reference fails to teach or suggest that xylanases resistant to the inhibitor are useful for preparing dough. Examiner respectfully disagrees with such a line of argument. The reference clearly teaches that the inhibitor is inherent in the wheat flour and therefore will be integral part of the dough. That teaching by itself would have been obvious to those skilled in the art to use such inhibitor and identify resistant xylanases. As the inhibitor is inherently found in the wheat flour the only option available for those skilled in the art would be to either remove the inhibitor from the dough, which could be a costly procedure, or identify xylanases that are resistant to the inhibitor. One skilled in the art would arrive at such a conclusion based on different degrees of inhibition observed for different xylanases. Applicant's argument that the reference fails to teach or suggest that xylanases resistant to the inhibitor are useful for preparing dough is highly misplaced since claim 26 is not directed to such a limitation.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392,

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170 USPQ 209 (CCPA 1971). In the instant case, Examiner has used the knowledge that is well known in the art in addition to what is specifically taught in the reference.

Next, applicant argues that the two amino acid sequences taught by Debyser et al. for the inhibitor does not match with the sequences provided in the claim. Such an argument is not persuasive because claim 26 is directed to the use of an inhibitor “wherein the inhibitor comprises *one or more* of the amino acid sequences”. Therefore, there is no requirement that SEQ ID 1 and 2 of the reference must match 100% with SEQ ID NO:13 or 15. Furthermore, as applicants have not provided the full length sequence of the inhibitor, Examiner continues to take the position that the inhibitor in the reference inherently comprises at least one of the sequences disclosed in claim 26.

Applicant also argues that Rouau et al. also does not teach or suggest the claimed invention. Applicant maintains that Rouau does not teach or suggest the isolated inhibitor to be useful to specifically identify and prepare one or more xylanases having a high degree of resistance to the inhibitor, as required by the claimed invention and that additionally, the reference fails to teach or suggest that xylanases resistant to the inhibitor are useful for preparing dough. In response, Examiner maintains that the reference clearly teaches the inhibitor to be inherent in the wheat flour and therefore will be integral part of the dough and from that teaching itself it would have been obvious to those skilled in the art to use such inhibitor to identify resistant xylanases. Applicant’s argument that the reference fails to teach or suggest that xylanases resistant to the inhibitor are useful for preparing dough is highly misplaced since claim 26 is not directed to such a limitation.

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Applicant also makes an issue with the "conclusions" of the reference arguing that Rouau expresses uncertainty regarding the cause of xylanase inhibition because Rouau states that "it cannot be totally excluded that the inhibitor is of microbial origin". It appears that applicant has misinterpreted the conclusion because, Rouau et al. actually states that "Although it cannot be totally excluded that the inhibitor is of microbial origin.....it may be reasonably assumed that this is one.....of the wheat grain". Contrary to applicant's conclusion, the above statement does not express any uncertainty. Other arguments by the applicant that the reference hints that the inhibitor could be a protease etc. are all irrelevant in the context of the above claim as the claim 26 is specifically drawn to a method of use of the inhibitor.

For all the above reasons Examiner continues to maintain the above rejection.

Conclusion

None of the claims are allowable.

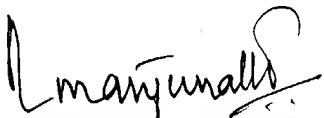
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
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July 28, 2004